

In accordance with the Examiner's request, a new complete claim set (including the amendments herein and newly added claims) is included as an attachment hereto. All amended claims are presented at the beginning, with editing marks included.

## **Drawings**

New drawings were submitted with the labeling requirements of the Draftperson's Review on 11 February 2003.

## **Claim Objections**

Claim 181 was objected to for grammatical reasons. Applicants have amended claim 181 to recite "claim 143" in place of "claims 143."

## **Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 135, 161, 166 and 169, along with claims dependent therefrom, were rejected as indefinite for use of the term "mammalian" in the preamble of these claims. In response, Applicants have amended these claims to recite "human" in the preambles.

Claim 172 was rejected for indefiniteness for use of the term "membrane" when such term is not recited in parent claim 169. In response, Applicants have amended claim 172 to recite that the ABC1 polypeptide of claim 169 is in the membrane of an intact cell.

Claim 176 was rejected for indefiniteness for use of the term "mutant hABC1 polypeptide" without mentioning whether the mutant polypeptide has biological activity

or the scope of the biological activities involved. In response, Claims 176 and 178 have been amended to recite that the mutant ABC1 has biological activity, as defined on page 15 lines 10-14.

Claim 184 was rejected as indefinite for use of the phrase "following said thereby." In response, Applicants have amended this claim to add the term "administering" after "following said."

Claim 168 was rejected as indefinite for dependence from cancelled claim 167. In response, Applicants have amended claim 188 to depend from claim 166.

Claim 188 was rejected as indefinite for dependence from cancelled claim 182. In response, Applicants have amended claim 188 to depend from claim 184.

**Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)**

Claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 were rejected under section 112 as failing to meet the written description requirement.

The rejection continues to argue that, although the polypeptides are not being claimed, the specification fail to disclose a sufficient number of ABC1 polypeptides to show that Applicants were in possession of the invention. In response, Applicants have amended the generic claims to clarify the polypeptide involved.

Claim 143 (and claims dependent therefrom) has been amended to recite a biological membrane comprising an ABC1 polypeptide with at least 85% identity to the amino acid sequence of SEQ ID NO: 1 and having lipid transport activity. This amendment is supported by the disclosure of the application as filed, especially at page 15, lines 8-9, where an ABC1 polypeptide is defined as "a polypeptide having

substantial identity to an ABC1 polypeptide having the amino acid sequence of SEQ ID NO: 1" and at page 12, lines 9-11, where "substantially identical" is defined as having preferably at least 85% identity. Thus, in defining the percent identity with human ABC1 of SEQ ID NO: 1 and the activity being assayed, Applicants believe that the grounds of the rejection have been overcome.

Applicants have also added new claims 226-228 depending from claim 143 and limiting percent identity to, respectively, 90%, 95% and having the sequence of SEQ ID NO: 1.

Claim 213 (and claims dependent therefrom) has been amended to add the limitation of lipid transporting activity and at least 85% identity of the ABC1 to SEQ ID NO: 1. Some additional modifications were made to this claim for purposes of clarifying the recited process but do not change the claim elements.

Applicants have also added new claims 229-231 depending from claim 213 and limiting percent identity to, respectively, 90%, 95% and 100%.

Claims 176 and 178 were rejected on similar grounds. In response, Applicants have amended claim 176 (and thus claim 178 also) by adding the limitation that the mutant ABC1 has ABC1 biological activity, said activity being defined in the application at page 15, lines 10-14, as well as throughout the application.

The remaining rejected claims all depend, either directly or indirectly, from either claim 143 or claim 213, which have been amended.

In the interests of clarity and continuity, claim 179 was amended to depend from claim 178 in place of claim 143 because a labeled hABC1 protein is useful in protein stability assays, such as with mutant ABCs more than in lipid transport (where it is the

lipid that might be labeled). This should have depended on claim 178 is supported in the specification at page 62, line 26 over to page 63, line 7.

**Rejection Under 35 U.S.C. §112, First Paragraph (Enablement)**

Claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 were rejected under section 112 as failing to meet the written description requirement.

The argument of the rejection is similar to that for written description: insufficient numbers of mammalian polypeptides have been disclosed in the application.

In response, Applicants note that this is the same set of claims rejected under the written description rejection and Applicants' response is substantially the same as that above with the same amendments overcoming this ground of rejection also.

No fee is believed due in filing this response. If any fee is due, the Commissioner is requested to charge such fees, or credit any refunds, to Deposit Acc't No. 03-0678.

<p align="center"><b>EXPRESS MAIL CERTIFICATE</b></p> <p>Express Mail Label No. EF010573581US</p> <p>Deposit Date: 6 March 2003</p> <p>I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above addressed to:</p> <p align="center"><b>BOX AF</b> <b>Commissioner for Patents</b> <b>Washington, DC 20231</b></p> <p><i>Alan J. Grant</i> <u>3/6/03</u> Alan J. Grant, Esq.      Date</p>
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Respectfully submitted,

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